



PATENT
Customer No. 22,852
Attorney Docket No. 04995.0053-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
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Shiv SRIVASTAVA et al.) Group Art Unit: 1643
)
Application No.: 10/802,823) Examiner: Stephen L. Rawlings
)
Filed: March 18, 2004) Confirmation No.: 5907
)
For: PROSTATE-SPECIFIC GENE,)
PCGEM1, AND METHODS OF)
USING PCGEM1 TO DETECT,)
TREAT, AND PREVENT)
PROSTATE CANCER)

**Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement mailed January 17, 2007, the Examiner required
restriction under 35 U.S.C. § 121 between:

- I. Claims 6-11 and 32-35, drawn to a method for detecting prostate cancer, classified, for example, in class 435, subclass 6;
- II. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 4, classified, for example, in class 536, subclass 23.1;
- III. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 6, classified, for example, in class 536, subclass 23.1;
- IV. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 7, classified, for example, in class 536, subclass 23.1;

- V. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 9, classified, for example, in class 536, subclass 23.1;
- VI. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 10, classified, for example, in class 536, subclass 23.1;
- VII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 11, classified, for example, in class 536, subclass 23.1;
- VIII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 12, classified, for example, in class 536, subclass 23.1;
- IX. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 13, classified, for example, in class 536, subclass 23.1;
- X. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 14, classified, for example, in class 536, subclass 23.1;
- XI. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 15, classified, for example, in class 536, subclass 23.1;
- XII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 16, classified, for example, in class 536, subclass 23.1;
- XIII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 17, classified, for example, in class 536, subclass 23.1;
- XIV. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 18, classified, for example, in class 536, subclass 23.1;
- XV. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 19, classified, for example, in class 536, subclass 23.1;
- XVI. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 20, classified, for example, in class 536, subclass 23.1;
- XVII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 21, classified, for example, in class 536, subclass 23.1;
- XVIII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 22, classified, for example, in class 536, subclass 23.1;
- XIX. Claims 20 and 21, drawn to a nucleic acid comprising at least 30 contiguous nucleotides of SEQ ID NO: 1, classified, for example, in class 536, subclass 23.1; or

XX. Claims 22-31, insofar as the claim is drawn to a method of detecting a PCGEM1 nucleic acid in a biological sample, classified, for example, in class 435, subclass 6.

Applicants provisionally elect to prosecute Group XX, claims 22-31, drawn to a method of detecting a PCGEM1 nucleic acid in a biological sample, with traverse.

Applicants believe that this requirement is improper. For a restriction requirement to be proper, the law requires that both (1) the inventions are independent and distinct, and (2) there would be a serious burden on the Examiner if restriction was not required. M.P.E.P. § 803. The Examiner has established neither.

The Examiner asserts that the inventions of Groups I and XX are patentably distinct because they:

- have different purposes or objectives;
- comprise different process steps;
- involve the measurement of different end points and establishment of different criteria; and
- have different criteria for success.

Office Action at 5. Applicants do not understand how these characterizations establish that the inventions of Groups I and XX are patentably distinct, particularly, where the claims of Groups I and XX are related process claims, sharing a common step of detecting hybridization between a nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO:1 and a PCGEM1 nucleic acid in a biological sample. Furthermore, the claims of Groups I and XX have been classified in the same field of search, i.e., class (435) and subclass (6).

As set forth in the M.P.E.P., related process inventions are distinct if:

- (A) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive;
- (B) the inventions as claimed are not obvious variants; and
- (C) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 802.01.

M.P.E.P. § 806.05(j). The Office has not established that any of these criteria apply and thus has failed to establish its burden of demonstrating that the inventions are distinct.

Having asserted that the inventions of Groups I and XX are patentably distinct, the Office then summarily concludes that “an examination of both would constitute a serious burden.” Office Action at 5. Applicants believe there would not be a serious burden in examining the claims of Groups I and XX together. Specifically, Groups I and XX are directed to related methods sharing a common detection step, and the Examiner has classified these claims in the same class (435) and subclasses (6). The Examiner further asserts that “the inventions of Groups I and XX have acquired a separate status in the art, as evidenced by their art-recognized divergence in subject matter.” Office Action at 5. Notably missing from the Examiner’s analysis, however, is any evidence of the alleged “art-recognized divergence in subject matter.” See M.P.E.P. § 808.02 (“Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.”) Given the classification of the claims into the same field of search and the absence of any evidence establishing a separate status in the art, Applicants believe it would not be an undue burden to search

the claims of Groups I and XX together. Thus, Applicants respectfully request that the restriction requirement be withdrawn.

The Examiner further required an election of species if Applicants elected Group I, specifically requesting Applicants to identify two or more nucleotide sequences from claim 8. Therefore, if the Examiner rejoins Groups I and XX, as requested, Applicants provisionally elect SEQ ID NO: 15 and SEQ ID NO: 22 with traverse. Claims 6 and 7 read on the elected species.

The M.P.E.P. requires the examination of a reasonable number of sequences, and states that up to ten independent and distinct amino acid or nucleotide sequences should be examined without restriction. M.P.E.P., § 803.04. Accordingly, if the claims of Groups I and XX are rejoined, Applicants submit that this election of species requirement (limited to a single pair of nucleotide sequences) is improper and request that all nucleotide sequences be examined together, or at a minimum that ten be searched.

Applicants note that upon allowance of a generic claim, they will be entitled to consideration of claims to additional species that are written in dependent form, or otherwise include all of the elements of an allowed generic claim as provided in 37 C.F.R. § 1.141. Office Action at 6.

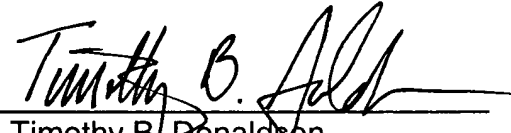
Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 7, 2007

By: _____


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